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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO	
09 927,463	08 13 2001	Florence Smadja-Joffe	1721-33	5388	
75	.90 11.18.2тиз				
NIXON & VANDERHYE P.C.			EXAMINER		
8th Floor 1100 North Glebe Road Arlington, VA 22201-4714			BELYAVSKYI	LYAVSKYI, MICHAIL A	
Armigion, VA			ART UNIT PAPER NUMBER		
			1644	10	
			DATE MAILED: 11-18-2002	10	

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)
		09/927,463	SMADJA-JOFFE ET AL.
Office Action Summary		Examiner	Art Unit
		Michail A Belyavskyi	1644
Period fe	The MAILING DATE of this communication apports Reply	pears on the cover sheet wit	h the correspondence address
A SH THE - Exte after - If the - If NO	IORTENED STATUTORY PERIOD FOR REPL'MAILING DATE OF THIS COMMUNICATION. Insions of time may be available under the provisions of 37 CFR 1 1 SIX (6) MONTHS from the mailing date of this communication. In period for reply specified above is less than thirty (30) days, a reply operiod for reply is specified above. The maximum statutory period to period for reply is specified above.	36(a) In no event, however, may a reply within the statutory minimum of thirty	(30) days will be considered timely
- Any	ire to reply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1 704(b)	Cause the application to become ARA	NDONED (25 H C C C 422)
1)	Responsive to communication(s) filed on 17 F	ebruary 2001 and 12 April	<u>2002</u> .
2a)□	This action is FINAL . 2b)⊠ Th	is action is non-final.	
3) Dispositi	Since this application is in condition for allowards closed in accordance with the practice under a con of Claims	ance except for formal matte Ex parte Quayle, 1935 C.D.	ers, prosecution as to the merits is . 11, 453 O.G. 213.
4)🖂	Claim(s) $\underline{12\text{-}27}$ is/are pending in the applicatio	n.	
	4a) Of the above claim(s) is/are withdrav	vn from consideration.	
5)	Claim(s) is/are allowed.		
6)	Claim(s) is/are rejected.		
7)	Claim(s) is/are objected to.		
8)⊠	Claim(s) 12-27 are subject to restriction and/or	election requirement.	
	on Papers		
9) 🗌 🧻	The specification is objected to by the Examiner		
10)[] 7	The drawing(s) filed on is/are: a)☐ accep	ted or b)□ objected to by the	Examiner.
	Applicant may not request that any objection to the		
11)[] T	he proposed drawing correction filed on		approved by the Examiner.
10) 🗔 –	If approved, corrected drawings are required in rep		
	he oath or declaration is objected to by the Exa	aminer.	
Priority u	nder 35 U.S.C. §§ 119 and 120		
13)🛛	Acknowledgment is made of a claim for foreign	priority under 35 U.S.C. § 1	119(a)-(d) or (f).
a)[☐ All b)☐ Some * c)☐ None of:		
	1. Certified copies of the priority documents	have been received.	
:	2. Certified copies of the priority documents	have been received in App	lication No
	3. Copies of the certified copies of the priorit application from the International Bure see the attached detailed Office action for a list o	eau (PCT Rule 17,2(a)).	-
	cknowledgment is made of a claim for domestic	·	
a)	☐ The translation of the foreign language proveknowledgment is made of a claim for domestic	isional application has beer	n received.
Attachment(; 120 ana/01 121.
2) 🔲 Notice	of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-948) ation Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Info	nmary (PTO-413) Paper No(s) rmal Patent Application (PTO-152) ction/Election fax .
Patent and Trac O-326 (Rev.	0.4.0.4%	on Summary	Part of Paper No. 17



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DETAILED ACTION

1. Applicant's amendments, filed 02/17/01 and 04/12/02(Paper Nos. 5 and 18), are acknowledged.

Claims 12-27 are pending.

In view of Applicant's Amendment filed on 02/17/01 (Paper NO:5) that was not timely entered, the previous Restriction Requirement mailed on 08/13/02 (Paper NO: 17) is hereby vacated. The new Restriction Requirement is set forth below. Examiner apologized for any inconveniences.

Restriction Requirement

- 2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
- I. Claims 12-26, drawn to a method of producing a medicinal product to induce or stimulate differentiation of leukaemic cells, classified in Class 424, subclass 184.1 and Class 514 subclass 54.
- II. Claims 12-26, drawn to a method of producing a medicinal product to induce or stimulate differentiation of CD 14CD15, classified in Class 424, subclass 184.1 and Class 514 subclass 54.
- III. Claims 27, drawn to a medicinal product to induce or stimulate differentiation of leukaemic cells, classified in Class 536 subclass 55.1.
- IV. Claims 27, drawn to a medicinal product to induce or stimulate differentiation of CD14CD15 cells, classified in Class 536 subclass 55.1.
- 3. Groups I and II are different methods. There inventions are different with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.



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3. Groups I/III and II/IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product, the polymer, can be made using chemical synthesizer or purified from human or non-human tissue.

4. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though the classification is shared, a different field of search would be required based upon distinct product recited and various methods of using this product comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

Species Election

5. Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

If Groups II is elected, applicant is required to elect a method of producing a medicinal product intended to induce or stimulate the differentiation of specific leukaemic cells, such as the ones recited in Claim 26.

These species are distinct because methods of producing a medicinal product intended to induce or stimulate the differentiation of specific leukaemic cells are differ with respect to method steps and endpoints. Thus each specific method employing a specific leukaemic cells recited in claim 26 represents patentably distinct subject matter and would require different searches in the scientific literature.

6. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

- 7. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.
- 8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).
- 9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskyi, Ph.D. Patent Examiner Technology Center 1600 November 18, 2002.

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600